THE NEUROSURGICAL CENTER OF SOUTHWEST VIRGINIA
DOCTORS OF NEUROLOGICAL SURGERY

Edgar N. Weaver, Sr., M.D. (1917-1989)
Edgar N. Weaver, Jr., M.D., FACS
James M. Vascik, M.D., FRCSC
Laurence I. Kleiner, M.D.
Raymond V. Harron, D.O.

5304 INDIAN GRAVE ROAD
SUITE A
ROANOKE, VA 24014-6608

Telephone 540-772-7107
800-289-4887
FAX 540-772-7858

GENERAL NEUROSURGERY
PEDIATRIC NEUROSURGERY
SPINAL SURGERY

July 11, 2000

Document Management Branch (HFA-305 Food and Drug Administration)
5630 Fisher's Lane
Room 1061
Rockville, MD 20852

RE: Proposed Regulations of Converting the Classification Of Human Tissues to Medical Devices

To Whom It May Concern:

This is a followup letter to one that I generated on December 7th, 1999, when I rendered my opinion about the regulation of bone grafts used as allografts from bone banks. I wish to reiterate this position. I cannot believe that this situation is still being considered after you have reviewed the position paper* on the use of bone dowels for human tissues. I continue to use tricortical iliac allografts. I have not run into any problems with quality concerns; it has proven to be efficacious and safe, and it is in the patient's best interest as alternatives of using autograft requires a longer surgery, added morbidity to the graft site, does not enhance fusion at all, and requires prolonged hospitalizations and costs in terms of operative time and hospitalization. As I have failed to see any evidence for any untoward infectious side effects from grafts in all my experience so far, I cannot see why this consideration is even being entertained to put more onus and burdensome regulation on a situation that is not a problem. As they say, "If it ain't broken don't fit it," I think this applies critically to any consideration of reclassifying human tissues to medical devices.

* AANS

Yours truly,

Laurence I. Kleiner, M.D.

LIK/pd

cc: David Feigal, M.D.
Director for Center of Devices for Radiologic Health
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

cc: Catherine Zoon
Director for Center for Biological Evaluation and Research

cc: C. Randall Mills
Regeneration Technologies, Inc.
1 Innovation Drive
Alachua, Florida 32615

97N-4845

C 490

WEAVER, VASCIK, KLEINER & HARRON
DOCTORS OF NEUROLOGICAL SURGERY
THE NEUROSURGICAL CENTER OF SOUTHWEST VIRGINIA
5304 INDIAN GRAVE ROAD, SUITE A
ROANOKE, VIRGINIA 24014-6608

ROANOKE
JUL 13'00
VA

U.S. POSTAGE
00.33
H METER 598150

Document Management Branch
HFA-305 Food and Drug Administration
Room 1061
Rockville, MD 20852

90 DECADE of the BRAIN 1990-2000